

JUL 21 2003

Appendix 1 - 510 (k) SUMMARY**510(k) summary for STRATO X****Identification**

Applicant	Villa Sistemi Medicali S.p.A. Via delle Azalee 3, 20090 BUCCINASCO - Milan- Italy Registration Number: 8021091
Contact Person	dr. Roberto Daglio – QA Director
Telephone (applicant)	+ 39 02 48859233
Designated Agent in the US	Andrew Hryndza Del Medical 11550 West King Street Franklin Park Illinois 60131 Tel. 847-288-7000 FAX <i>847-288-7911</i>
Manufacturing site	Villa Sistemi Medicali S.p.A. Via delle Azalee 3, 20090 BUCCINASCO - Milan - Italy

Trade name: ENDOS DC**Common name:** ENDOS DC**Classification name:** according to 21 CFR 872-1800, ENDOS DC is in
Class II.**Substantial equivalent device:** the ENDOS DC is defined as Substantially
Equivalent (SE) to the GENDEX DENTSPLY model 765DC. The predicate
device has been approved by FDA and has 510(k) approval number K992610

The following table compares the ENDOS DC V with the predicate device

	ENDOS DC	GENDEX 765 DC
Intended use	extra oral source X-ray system for dental radiographic examination of the teeth	extra oral source X-ray system for dental radiographic examination
High Voltage value	65 kV _p +/- 5%	65 kV _p +/- 3kV
Tube current	4-5 mA +/- 5%	7 mA +/- 5%
Focal spot size	0.7 mm (IEC 336)	0.4 mm (IEC 336)
Anode inclination	19°	12.5°
Total filtration	> 2.0 mm Al	2.0 mm Al
HVL	> 1.5 mm Al	2.0 mm Al
H.V. generator:	High frequency	High frequency
X-Ray exposure time control	Automatic – pre-programmed Microprocessor Controlled	Automatic – pre-programmed Microprocessor Controlled
X-Ray exposure timing	0.010 sec to 2 sec	0.020 sec to 2 sec
Electrical characteristics	120 V 4.5 impulsive A max	120 V 5 impulsive A max
Focus film distance	> 20 cm or > 30cm	> 20 cm or > 30cm
Leakage radiation	< 25 mR/h at 1 meter from focus	< 28 mR/h at 1 meter from focus
X-ray beam dimension at 20cm	< 6cm	< 6cm
Safety features	Dead man command	Dead man command
Signaling devices	Acoustic and visual signal	Acoustic and visual signal

Indication for use.

The indication for use of the ENDOS DC is: : **extra oral source X-ray system** for dental radiographic examination and diagnosis of diseases of the teeth.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2003

Mr. Roberto Daglio
QA Director
Villa Sistemi Medicali
via Azalee 3
20090 Buccinasco, Milan
ITALY

Re: K030634
Trade/Device Name: ENDOS DC
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source
x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: May 7, 2003
Received: May 9, 2003

Dear Mr. Daglio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

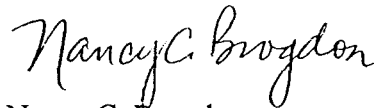
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.1. Indication for use Statement

510(k) Number: K 030634

Device Name: **ENDOS DC**

The indication for use of the ENDOS DC is: : **extra oral source X-ray system** for dental radiographic examination and diagnosis of diseases of the teeth.

used as:

prescription only: ✓

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030634